

### **REMARKS**

Applicants thank the Examiner for issuing this Supplemental Office Action to replace the non-final Office Action dated 4 April 2005. Applicants thank the Examiner for withdrawing the finality of the previous Office Action pursuant to 37 CFR 1.114, and for considering Applicants' March 2, 2005 response. Claims 4, 5, 9-15, 31-34, 44, 47-50, 54, and 98-128 are pending in the present application. Claims 4, 31, and 43 are amended. Support for this amendment may be found throughout the application, and, in particular, for example, at page 15, lines 20-22. This amendment is meant to clarify, not narrow, the scope of the claims.

### **Information Disclosure Statement**

Applicants thank the Examiner for considering the Information Disclosure Statement filed 2 March 2005 and for returning a signed copy of PTO form 1449. Applicants wish to call the Examiners' attention to a Supplemental IDS filed in the present case on October 6, 2005, and respectfully request consideration of this additional IDS.

### **Claim Rejections – 35 USC §103**

Claims 4, 5, 9-15, 31, 43, 44, 47-50 and 109-128 were rejected by the Examiner under 35 USC 103(a) as unpatentable over Campbell et al. (WO 98/35609), further in view of Clausen et al. (Journal of Clinical Investigation (1996) Vol. 98, No. 5, pages 1195-1209).

Applicants respectfully traverse this rejection and request that the rejection of these claims be withdrawn. In brief, the Examiner has not met the burden of providing a prima facie case. The Campbell reference does not teach selecting data from only individuals that have not been pre-selected for any particular disease. Campbell further does not provide any motivation to be combined with the Clausen reference, nor does Clausen provide a similar motivation. Even if one were to combine the references, Clausen does not teach the subject matter deficient in Campbell. Clausen merely studies particular known insulin sensitivity-related factors in a healthy population. None of the references cited by the Examiner, either alone, or in combination, teach the creation of a healthy patient database of the present claims.

In the pending Office Action, the Examiner stated “Campbell et al. teach a computer-based system for predicting the future health of an individual based upon acquiring and analyzing a number of biological and physiological biomarkers.” (Office Action at 4)

Indeed, Campbell, in the Field of the Invention (page 1), states that

the present invention predicts the future health of an individual by obtaining longitudinal data for a large number of biomarkers from a large human test population, statistically selecting predictive biomarkers, and determining and assessing an appropriate multivariate evaluation function based upon the selected biomarkers.

The Examiner stated that Campbell teaches a system comprising a “method of obtaining data from healthy members of the population. In particular, the term ‘specified biological condition of the invention includes all ranges of health, from the most robustly healthy to the most severely diseased (page 22, lines 13-16).” (15 July 2005 Office Action at 4)

But, in contrast to the pending claims, the Examiner stated “Campbell et al. do not specifically teach only data from individuals that have not been pre-selected for any particular disease.” In fact, as noted by the Examiner in the earlier April 4, 2005 Office Action, the population used for the database in Campbell et al. “consists of two subpopulations, those having acquired a specified biological condition and those not having acquired the specified biological condition,” (citing the Abstract). Thus, Campbell does not teach or suggest methods or systems related to a healthy database, that includes data from only healthy members of a population of organisms not manifesting any disease state and where the members are not pre-selected on the basis of sharing a common disease.

The Examiner cited the Clausen reference as teaching that

studying only healthy members of a population is beneficial. In particular, Clausen et al. studied the distribution of the insulin sensitivity index, the acute insulin response, and the glucose effect in young healthy Caucasians in an effort to estimate the impact of anthropometric and environmental determinants on these variables. (Office Action at 5, citing the Abstract)

The Examiner stated that it would have been

prima facie obvious to one of ordinary skill in the art at the time of invention to have included only healthy individual data, as was acquired by Clausen et al., in the database of Campbell et al., as motivated by the statement that “it would be desirable if the onset

of future health problems could be predicted for an individual with sufficient reliability far enough into the future so that the chances could be increased for preventing future health problems for the individual rather than waiting for actual onset of a disease and then treating the symptoms. (Office Action at 5-6, citing Campbell, page 1, line 15-18)

Applicants respectfully disagree with the Examiner's conclusion. First, Campbell teaches a comparison of sets of data from two subpopulations, Campbell does not obtain data only from individuals that are not selected on the bases of having a particular disease or other characteristic. Thus, even if the definition of "specified biological condition" were to be interpreted as including only "robustly healthy" individuals, because Campbell teaches the comparison of two different subpopulations, there must be some distinction as to the health of the two "robustly healthy" groups, that is, one of the groups would have some type of condition or characteristic even if the individuals of that group were still healthy. There is no motivation in Campbell to combine its teaching with any teaching of taking data from just one pool of subjects, none of which having been selected for having a particular disease or other characteristic. Thus, there is no motivation in Campbell to combine its teachings with, for example, the Clausen reference.

Further, Clausen does not provide any motivation to combine its teachings with Campbell. Clausen reviews the distribution of known biomarkers, such as insulin sensitivity, in healthy patients. The subtitle for the Clausen article is "Analysis of the impact of gender, body fat, physical fitness, and life-style factors." Clausen analyzes known markers for diabetes, such as low insulin sensitivity "in prospective studies low insulin sensitivity has been found to be a risk factor for the subsequent development of non-insulin dependent diabetes mellitus (NIDDM)." (Clausen at 1) Thus, although Clausen studies apparently healthy individuals, Clausen is attempting to correlate environmental and other factors with the appearance of a particular known biomarker for diabetes—low insulin sensitivity. Clausen does not teach or suggest the desirability of identifying new biomarkers by comparing two subpopulations, one healthy, and one manifesting some type of disease or other characteristic.

Even if there were a motivation to combine Campbell with Clausen, Clausen does not teach the deficiencies of Campbell. A reference that discusses obtaining data from a healthy population, in combination with Campbell, does not result in the subject matter of the pending claims. The pending claims teach to one database, including data from individuals that have not

been selected for having a particular disease or other characteristic, not a database created to compare two subpopulations, at least one of which having been selected for having some sort of disease or condition.

Thus, in regard to claims 4, 5, 9-15, 31, 43, 44, 47-50, and 109-128, Applicants respectfully request that the Examiner withdraw the rejection of these claims.

Claims 32-34, 98-100, and 102 were rejected under 35 USC 103(a) as unpatentable over EP 0596205 A2 (Bullaughay et al) in view of Campbell et al. (WO 98/35609), in view of Clausen et al. (Journal of Clinical Investigation (1996) Vol. 98, No. 5, pages 1195-1209), in further view of US 5,498,545 (Vestal). Bullaughay, which "teaches an analytical system for coordinating the operations of various hardware instruments in carrying out a bench method or bench sequence," and Vestal, which "teaches a system for analyzing multiple samples by mass spectrometry," do not provide the deficient teachings or motivation noted above regarding Campbell and Clausen. Thus, Applicants respectfully request that the Examiner withdraw the rejection of claims 32-34, 98-100, and 102.

Claims 54 and 101 were rejected under 35 USC 103(a) as unpatentable over EP 0596205 A2 (Bullaughay et al.), in view of Campbell et al. (WO 98/35609), in further view of Clausen et al. (Journal of Clinical Investigation (1996) Vol. 98, No. 5, pages 1195-1209). Again, Bullaughay does not provide the deficient teachings or motivation noted above regarding Campbell and Clausen, Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 54 and 101.

Claim 98 was rejected under 35 USC 103(a) as unpatentable over Campbell et al. (WO 98/35609), in view of Clausen et al. (Journal of Clinical Investigation (1996) Vol. 98, No. 5, in further view of US 5,498,545 (Vestal). As noted above, Vestal does not provide the deficient teachings or motivation regarding Campbell and Clausen. Applicants therefore respectfully request that the Examiner withdraw the rejection of claim 98.

Claims 103-108 were rejected under 35 USC 103(a) as unpatentable over EP 0596205 A2 (Bullaughay et al), in view of Campbell et al. (WO 98/35609), in view of Clausen et al. (Journal of Clinical Investigation (1996), Vol. 98, No. 5, pages 1195-1209), in view of US 5,498,545 (Vestal), as applied to claims 100 and 102, in further view of US 6,602,662 B1 (Koster). As stated above, Vestal does not provide the deficient teachings or motivation regarding Campbell and Clausen. Koster, which teaches "a mass-spectrometry based process for detecting nucleic

acid molecules and sequences in the molecules," does not provide this missing teaching or motivation. Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 103-108.

**CONCLUSION**

Applicants respectfully submit that, after entry of the amendment above, all pending claims will be in condition for allowance, and they earnestly solicit an early notice to such effect. That said, should any issues or questions remain, the Examiner is encouraged to telephone the undersigned at (858) 623-9470 so that they may be promptly resolved.

Respectfully submitted,

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